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Docket No.: 203970US6PCT

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

RE: Application Serial No.: 09/807,413
Applicants: Marco FALCIANI, et al.
Filing Date: April 19, 2001
For: BAG FOR PRESERVING AND TRANSPORTING STERILE PRODUCTS IN POWDER FORM AND FOR FORMING SOLUTIONS OF SAID PRODUCTS IN THE BAG
Group Art Unit: 3749
Examiner: Basichas, A.

SIR:

Attached hereto for filing are the following papers:

APPEAL BRIEF (in triplicate)

Our credit card payment form in the amount of **$330.00** is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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DOCKET NO: 203970US6PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF	:
MARCO FALCIANI, ET AL.	: EXAMINER: BASICHAS, A.
SERIAL NO: 09/807,413	:
FILED: APRIL 19, 2001	: GROUP ART UNIT: 3749
FOR: BAG FOR PRESERVING AND TRANSPORTING STERILE PRODUCTS IN POWDER FORM AND FOR FORMING SOLUTIONS OF SAID PRODUCTS IN THE BAG	:

APPEAL BRIEF

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicants appeal the outstanding Final Rejection of December 3, 2003, finally rejected each of pending claims 6-25.

I. REAL PARTY IN INTEREST

The above-noted application is assigned to ACS Dobfar S.p.A., which is the real party in interest, having a place of business at Viale Addetta, 6/8/10 20067 Tribiano (MI), Italy.

II. RELATED APPEALS AND INTERFERENCES

Applicant and applicants'' representative are not aware of any related appeals or interferences that will directly effect or be directly affected by or having a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 6-25 are pending in this application and the rejection of each of claims 6-25 is being appealed.

Claims 1-5 were canceled during prosecution of the application.

IV. STATUS OF AMENDMENTS

No amendment was filed subsequent to the Final Rejection of December 3, 2003.

V. SUMMARY OF THE INVENTION

The applicants of the present invention recognized that a problem exists in the current art in that until the present invention it was not possible to have a bag in which a ready to use solution could be reconstituted from a sterile product in powder form such that the sterile product in powder form could be reconstituted directly into the bag still under sterile conditions to form solutions that could then be taken out from the bag as a whole all at one time or as partial portions (e.g., single doses) of the total volume of the reconstituted solution. (Substitute specification page 4, lines 5-12).

As discussed in the present specification, a bag in which a sterile product in powder form is contained and which must be completely filled with a solvent to form a solution has been realized. (Substitute specification, page 3, lines 12-14). However, the drawback with that type of device is that since the bag must be completely filled with the solvent a complete solution of the powder cannot be attained by simply shaking the bag, and therefore the bag typically requires additional devices for creating turbulence within the bag. (Substitute specification, page 3, lines 14-19). Further, since the bag is always completely filled with the solvent, the bag must always start out with the same amount of soluble sterile product in order to get the final desired concentration.

To make the explanation of the claimed invention simplified, as a concrete example imagine that a sterile product in powder form to be stored within the bag is a crystalline antibiotic to be used for reconstituting injectable solutions in which the concentration of the antibiotic material must be exactly controlled at a specified value.

Before the claimed invention was made and exploited, it was also common practice to use glass bottles containing single doses of antibiotic that was dissolved directly within the bottles by feeding water into the bottles. The thereby formed single dose solutions were then drawn into syringes to be injected into patents. Such an operation is demanding and costly, particularly at hospitals were such an operation has to be repeated a large number of times everyday. (Substitute specification, page 2, lines 17-31).

It is not believed currently possible to prepare solutions of antibiotics in bags in suitable plants to then dispatch them to hospitals, because such solutions remain unaltered for a very short time. (Substitute specification, page 3, lines 1-4).

Claims 6-11 set forth, and with reference to Figures 1-5 as a non-limiting example, an improved bag 1 such that the volume of the bag 1 is larger than the volume of the reconstituted ready to use solution after the reconstitution. (Substitute specification, page 6, lines 11-14, and page 7, lines 6-7 and 29-30). That is, in the bag 1 of the noted claims after a solvent is introduced into the bag and mixes with the soluble sterile product 10 in the bag 1, the reconstituted solution only partially fills a capacity of the bag 1. That allows the bag to be easily shaken to achieve a proper solution. (Substitute specification, page 7, lines 7-9). That also allows different quantities of soluble sterile product to be initially placed in the bag. (Substitute specification, page 7, lines 9-11).

Further, the bag 1 is hermetically sealed at its periphery to define a sterile closed space and has at least one port 2, 4 also of polyolefin construction defining a passageway having two ends that open inside and respectively outside the bag 1. The passageway is

closed by a pierceable membrane 6, 7 for introduction of a solvent into the bag 1 and respectively for withdrawal of the read to use solution from the bag 1.

Further, the bag 1 includes a port that has a plug 20. With that structure the reconstituted liquid can be removed by piercing a syringe port through the plug 20 and withdrawing the reconstituted solution from the bag 1. The plug 20 provides a structure such that when the syringe needle is removed the reconstituted solution in the bag 1 is not able to flow out of the bag 1. (Substitute specification, page 8, lines 8-13).

Claims 12-17 are similar to claim 6 except that claims 12, 14, and 17 are specifically directed to a "method for preparing solutions with predetermined concentrations of soluble sterile product in powder form". According to the methods of claims 12-17, a step is executed for feeding an amount of solvent into the bag that is less than the capacity of the bag, and individual doses of the reconstituted solution are then removed from the bag. The bag can specifically hold a multiple of single doses of the ready to use solution directly usable for practical utilization.

Certain claims, for example dependent claims 18 and 19, depend from respective independent claims 14 and 16 and clarify that "the fed amount of solvent is 2/3 to 1/2 of the capacity of the bag". That subject matter is noted in the specification for example at page 7, first full paragraph, indicating that the bag capacity is preferably 1.5 and 2 times the volume of the solution to be prepared in it, see also claims 7 and 10. Claims 18 and 19 recite the inverse of that feature by indicating that the fed amount of solvent is 2/3 to 1/2 of the capacity of the bag.

Claims 20-25 are similar to claims 14-17 except that those claims are directed to "a method for using a sterile bag...". In the methods recited in claims 20-25 an operation is still executed of feeding an amount of solvent into the bag that is less than the capacity of the bag,

and an operation is then executed for removing individual doses of the reconstituted solution from the bag.

VI. ISSUES

The only issue outstanding in the above-identified application is whether the combination of teachings in U.S. patent 4,550,825 to Sutryn et al. (herein "Sutryn") or U.S. patent 5,257,986 to Herbert et al. (herein "Herbert") and further in view of U.S. patent 3,647,386 to Gilford renders obvious the subject matter of each claims 6-25 under 35 U.S.C. § 103(a).

VII. GROUPING OF CLAIMS

Claims 6-11 are grouped together as a first group as presented in the arguments below.

Claims 12-25 are grouped together as a second group as argued below.

Claims 7, 10, 18, 19, 22, and 25 further distinguish over the applied art, and are also grouped together as a further group as argued below.

Claims 8, 11, 13, 15, 17, 21, and 24 further distinguish over the applied art, and are also grouped together as a further group as argued below.

VIII. ARGUMENT

Claims 6-11

In supporting the outstanding rejection to each of the claims the Final Rejection states:

> Sutryn and Herbert disclose a hermetically sealed polyolefin bag for preserving and transporting a soluble sterile product in powder form and for reconstituting in the bag a ready to use solution with a predetermined concentration of the sterile

> product. Sutryn and Herbert do not specifically state that the water should only be added to a volume less than the capacity of the bag. Adding less than the full capacity of the bag in order to allow for room to shake is well within the knowledge and ability of one of ordinary skill in the art; it is a simple matter of common sense.[1]

The above-noted grounds for the outstanding rejection does not fully consider each limitation recited in claims 6-11, and improperly ignores features recited in claims 6-11.

In independent claim 6 the claimed bag is hermetically sealed and the bag itself "contains an amount of the sterile product in powder form". Similarly, independent claim 9 recites "the sealed bag originally containing a dosed amount of a soluble sterile product in powder form". As is clear from those features recited in each of independent claims 6 and 9, and thereby the claims dependent therefrom, the bag itself is sealed to originally contain the soluble solution in powder form. As shown for example in Figure 3 in the present specification as a non-limiting example, the bag 1 originally contains the soluble sterile product in powder form 10, before the solution is input to the bag 1. That structure itself differs from the teachings in both Sutryn and Herbert.

Sutryn is directed to a multicomponent medicament container in which a soluble product is stored in a special dry medicament compartment closed by a closure plug 42 and is introduced into the fixed amount of solvent 38, see for example Figures 2-3 of Sutryn and the disclosure at column 4, line 59 et seq.

Similarly to Sutryn, Herbert discloses a structure in which a powder substance 17 is stored in its own chamber 2 and is also introduced into a bag containing a fixed amount of carrier solution 18.

In such ways, both Sutryn and Herbert are directed to similar devices in which a powder product is introduced from a separate compartment into a fixed amount of liquid in a bag.

---

[1] Final Rejection of December 3, 2003, page 3, lines 3-9 of prenumbered paragraph 4.

In contrast to the teachings in each of Sutryn and Herbert, in independent claims 6 and 9 the bag itself originally contains the sterile product in powder form, and the soluble sterile product is introduced into the bag. In that way, those claims clearly differ from the teaching in Sutryn and Herbert, and no teachings in Gilford can overcome those noted deficiencies of Sutryn in view of Herbert.

Further, applicants respectfully submit that the outstanding rejection improperly dismisses the claimed features that when the sterile product in powder form and solvent are mixed such as solution "only partially fill[s] a capacity of the bag" as recited in independent claim 6, or that "the capacity of the sealed bag is larger than the volume of the ready to use solution after the ready to use solution is reconstituted in the sealed bag", as recited in independent claim 9.

The Final Rejection summarily dismisses that feature as "a simple matter of common sense". However, applicants traverse that position.

First, the outstanding rejection is clearly improper in not setting forth a proper *prima facie* case of obviousness.

As noted in M.P.E.P. § 2143:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.
>
> The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicants' disclosure.

With respect to the above-noted feature of the bag being only partially filled the outstanding Final Rejection has clearly not set forth a proper *prima facie* case of obviousness.

First, there is no suggestion or motivation in any reference or knowledge generally available to one of ordinary skill in the art to add less fluid than the full capacity of the bag. Second, there is no indication that utilizing such a feature would provide any expectation of success or benefit in the devices of Sutryn or Herbert, and in fact as discussed further below applicants respectfully submit that such a feature is contrary and not beneficial to the teachings in those references. Also, clearly the prior art references themselves do not teach or suggest such features. Clearly the only teaching or suggestion to utilize such a structure is from applicants' own disclosure. Thus, none of the criteria noted above to establish a proper *prima facie* case of obviousness has been set forth with respect to claims 6-11.

A significant benefit of the structure of the claimed invention is that it allows different quantities of soluble, sterile product to be initially placed in a bag. In the devices of Sutryn and Herbert cited for the rejection, the bags are initially completely filled with an initial amount of solvent, and thus they must always have the same initial amount of powder product therein to achieve a desired concentration. In contrast, in the claimed invention, since the bag is designed to be only partially filled, a different amount of sterile product can be introduced into the bag.

In the devices of Sutryn and Herbert, a quantity of the powder product provided in the chambers and to be introduced into the bag is initially specifically selected so that when those powder products are introduced into the bag an appropriate concentration is realized. By only partially filling the bags in Sutryn and Herbert without making any further adjustments the desired appropriate concentration would not be achieved.

Applicants also note that what the Examiner has stated as "a simple matter of common sense" is a feature that the Examiner has not been able to find in any prior art reference. Prior to the outstanding rejection the Examiner set forth other rejections based on other cited art of U.S. patent 5,385,564 to Slater et al. (herein "Slater"), U.S. patent 5,484,431

to Scharf et al. (herein "Scharf"), U.S. patent 4,282,863 to Beigler et al. (herein "Beigler"), and U.S. patent 3,726,276 to Schumann et al. (herein "Schumann"). At that point the Examiner also maintained the position that only partially filling the bag was a "simple matter of common sense". However, applicants note that with respect to what the Examiner has consistently stated as "a simple matter of common sense", the Examiner has not been able to find ***any*** prior art reference to teach or suggest such a feature.[2]

Applicants note that what the Examiner summarily disregards as "a simple matter of common sense" is clearly a unique feature that has not been found in any prior art reference, and it is clearly improper for that positively recited feature to be not properly considered as in the Final Rejection.

Further along those lines, what the outstanding Final Rejection disregards as obvious or "simple common sense" is clearly not obvious or simple common sense as it is ***contrary to what is actually taught in the applied references***. That is, each of the applied references to Sutryn, Herbert, and Gilford only disclose completely filling a bag. As that is the case, it is unclear how the Final Rejection can indicate that a directly contrary operation to that actually disclosed in each of the cited references would be "simple common sense". Stated another way, how can it be "simple common sense" to do something contrary to the teachings in each of the cited references. It is respectfully submitted that, in fact, the applicants of the present invention have recognized drawbacks in conventional devices such as in the cited art, and have devised the novel solution of the present invention to address such drawbacks.

The claims are directed to storing a soluble solid product within a bag whose capacity is larger than the volume of the solution to be reconstituted therein. With the use of such a large bag, there is no need for the bag to have special shapes or include special devices to

[2] Seven references have at some time been applied against the claims, not one of which teaches what the Examiner states is "common sense"; and in fact all the cited references disclose the opposite to what the Examiner states is "common sense".

ensure proper solution of the soluble solid product in a solvent because the solid product can be quickly and completely dissolved by simply vigorously shaking the bags.

A second significant advantage achieved by the claimed invention, and which has been completely ignored in the Final Rejection, is that by designing a bag to be only partially filled different number of doses of the ready to use solution can be stored in the bag. That is, the structure of the claimed bag allows different amounts of powder to be initially placed in the bag, and combining that with the fact that different amounts of solution can be introduced into the bag (because of the oversizing of the bag), multiple doses of the ready to use solution can be reconstituted in the bag. As an example, based on the amount of sterile powder initially placed in the bag and the amount of solvent introduced into the bag the bag can contain 1, 5, 10, etc. doses of the ready to use solution, which can be easily distributed. That provides significant benefits over a conventional system utilizing glass bottles containing single doses of, for example, an antibiotic. As noted above, the applicants of the present invention recognize that such a conventional approach is demanding and costly as it requires utilizing may individual glass bottles, each requiring handling. In the claimed invention multiple doses can be realized from a single bag and can be withdrawn from the single bag in individual dose levels.

Such an operation and structure are neither taught nor suggested by any of the applied art to Sutryn, Herbert, and Gilford.

Obviously, when utilizing such a bag as claimed it is necessary to exactly measure the amount of solvent to be fed into the bag containing a measured amount of soluble solid compound. However, applicants submit that the benefits of the claimed invention overcome such a drawback as it is a simple, quick operation to introduce a desired dose volume of solvent into a bag, while it is of great practical importance to have the possibility of completely and quickly dissolving a soluble product originally stored in the bag.

Further, what is considered in the Final Rejection to be "common sense" would actually result in a drawback in the devices of Sutryn, Herbert, and Gilford. Specifically, in those devices, by completely filling the bags therein, it is not necessary to measure a volume of a solvent to be injected into the bags. Instead, the bags must just be completely filled.

In contrast to the teachings in Sutryn, Herbert, and Gilford, the claimed invention requires an extra step of properly measuring an amount of solvent to be introduced into the bag since the bag is not completely filled with the solvent. However, the applicants believe that the benefits of the present invention outweigh that inconvenience.

In such ways, applicants respectfully submit that clearly independent claims 6 and 9, and the claims dependent therefrom, patentably distinguish over the applied art, and that therefore claims 6-11 are allowable.

Claims 12-15

Initially, applicants note that claims 12-25 also distinguish over the teachings in the Final Rejection for similar reasons as discussed above with respect to claims 6-11 as claims 12-25 also require the combination of the powdery substance and soluble solution not completely filling the bag or, for example, as recited in claim 12, "the capacity of the bag being larger than the volume of the ready to use solution after the ready to use solution is reconstituted in the bag". As discussed above with respect to claims 6-11 such features distinguish over the applied art, and are similarly recited in the other independent claims.

The Final Rejection, however, is even more deficient when it comes to claims 12-25 that are directed to a method of preparing solutions or a method of using a sterile bag. The rejections are further deficient as in each of claims 12-25 a step is required of ***feeding solution into a bag containing a dosed amount of soluble sterile product***, and then

removing individual dose sizes from the bag. Such features clearly further distinguish over the applied art.

First, applicants note that as discussed above both of the primary cited references to Sutryn and Herbert disclose an operation in which a bag initially contains a solvent and a powdery substance is introduced into the bag. That feature is directly contrary to what is recited in claims 12-25. For example, independent claim 12 recites "feeding into the bag, containing a dosed amount of soluble sterile product in powder form... an amount of solvent... ". The other independent claims 14, 16, 20, and 23 recite a similar feature. That feature itself is clearly neither taught nor suggested by the applied art and is not even addressed in the Final Rejection.

Both Sutryn and Herbert clearly disclose an operation of placing powder substance into a bag already containing the solvent, and the above-noted claims require a ***contrary operation of feeding a proper amount of solvent into a bag already containing a dosed amount of soluble sterile product***. Thus, clearly the outstanding rejection is improper for that reason alone and must be withdrawn.

Claims 12-25 further recite the step of "removing from the bag the reconstituted ready to use solution in individual dose sizes". To address that feature the Final Rejection cites the teachings in Gilford. However, applicants respectfully submit that it would not at all have been obvious to one of ordinary skill in the art to combine the teachings of Gilford to the teachings in Sutryn and Herbert, and that such a combination does not meet the claimed limitations.

First, Gilford is not directed to the same type of device as in Sutryn and Herbert. Gilford is directed to a sample processing container and is not at all directed to a bag that mixes a powdery substance with a solvent as in Sutryn and Herbert. The only motivation set

forth in the Final Rejection to make such a combination of teaching is "for the purpose of sampling the contents of the bag" in Sutryn and Herbert.[3]

However, in that regard applicants note that Sutryn and Herbert are not directed to sample containers, in contrast to Gilford. Gilford is specifically designed to store samples that must be evaluated and therefore removed. There is no "***single dose***" (emphasis added) considered in the device of Gilford because Gilford is not directed to storing a solution that is to be applied to a patient in dosages.

In such ways, the teachings in Gilford have no relevance whatsoever to the teachings in either Sutryn or Herbert, and Gilford itself also does not teach or suggest removing from the bag the reconstituted ready to use solution in individual dose sizes.

Gilford discloses removing portions of the sample, but not even in individual dose sizes. It would be nonsensical to Gilford to even consider removing solutions in individual dose sizes because Gilford is not directed to storing a solution to be provided to a patient as a dosage.

The Final Rejection, thereby, improperly fails to consider the complete differences in objectives, operations, and teachings in Gilford relative to Sutryn and Herbert.

For the foregoing reasons, applicants respectfully submit that each of claims 12-25 even further distinguishes over the applied art, and that therefore each of claims 12-25 are allowable.

Claims 7, 10, 18, 19, 23, and 25

Applicants also respectfully submit that the outstanding rejection has not properly considered certain features in the dependent claims, such as "the capacity of the bag is between 1.5 and 2 times a volume of the of the ready to use solution... reconstituted in the

[3] Final Rejection of December 3, 2003, last two lines of prenumbered paragraph 4.

bag" as recited in claims 7 and 10, and "the feed amount of solvent is 2/3 to1/2 of the capacity of the bag" as recited in claims 18, 19, 22, and 25.

The Final Rejection summarily dismisses that feature as "discovering the optimal workable ranges" which "involves only routine skill in the art."[4] However, applicants traverse that position.

More particularly, it is only applicants of the present invention that have recognized expanding a capacity of a bag relative to solvents introduced therein. Further, since Sutryn and Herbert merely disclose completely filling a bag it is unclear how or why significantly limiting the filling of a bag could be considered an optimal workable range.

Applicants also note that it is usually with precision that a bag must be filled in devices such as in Sutryn and Herbert to ensure that the reconstituted solvent has the appropriate concentration. Clearly in medical applications having an improper concentration is a significant problem. Thus, the Final Rejection is clearly improper in summarily dismissing the capacity of the bag relative to the amount of solvent as in the claims, as such a feature must be precisely controlled in the noted references to Sutryn and Herbert.

For these foregoing reasons, applicants respectfully submit that each of dependent claims 7, 10, 18, 19, 22, and 25 even further distinguish over the applied art, and that those claims are even further allowable.

Claims 8, 11, 13, 15, 17, 21, and 24

Each of dependent claims 8, 11, 13, 15, 17, 21, and 24 are believed to even further distinguish over the applied art as those claims further recite that the volume of the ready to use solution reconstituted in the bag is a "multiple of single doses of the ready to use solution directly usable for practical utilization". That feature has not even been addressed in the

[4] Final Rejection of December 3, 2003, page 3, lines 9-18 of prenumbered paragraph 4.

Final Rejection. The only indication in the Final Rejection of utilizing plural doses is the reliance on the teachings in Gilford. However, as noted above Gilford is merely directed to a sample processing container and is not at all directed to a bag that includes a solution to be given doses. It appears clear the Final Rejection has completely disregarded the above-noted features further recited in dependent claims 8, 11, 13, 15, 17, 21, and 24. Those claims even further recite that multiple of single doses are stored in the bag. For example a bag can contain 1, 5, 10, etc. doses for a practical utilization. Clearly such a feature is neither taught nor suggested by Gilford and again is not even addressed in the Final Rejection.

Thus, dependent claims 8, 11, 13, 15, 17, 21, and 24 are believed to even further distinguish over the applied art, and thus those claims are believed to be further allowable.

IX. CONCLUSION

For the foregoing reasons, applicants respectfully submit that each of claims 6-25 patentably distinguishes over the combination of teachings of Sutryn or Herbert and further in view of Gilford. Therefore, the outstanding rejection must be REVERSED.

Respectfully submitted,

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APPENDIX

Claims 1-5 (Canceled)

Claim 6 (Previously Presented): A bag for preserving and transporting a soluble sterile product in powder form and for reconstituting in the bag a ready to use solution with a predetermined concentration of the sterile product,

the bag being of polyolefin construction;

the bag being hermetically sealed at its periphery to define a sterile closed space and having at least one port also of polyolefin construction defining a passageway having two ends that open inside and respectively outside the bag, the passageway being closed by a pierceable membrane for introduction of a solvent into the bag and respectively for withdrawal of the ready to use solution from the bag,

wherein the bag contains an amount of the sterile product in powder form adapted to give with the solvent and within the bag the reconstituted ready to use solution only partially filling a capacity of the bag, and

wherein the at least one port of the bag is plugged by a plug, the plug configured to receive a syringe port through the plug to remove the reconstituted ready to use solution from the bag.

Claim 7 (Previously Presented): A bag according to claim 6, wherein the amount of the sterile product in powder form enclosed within the bag is such that the capacity of the bag is between 1.5 and 2 times a volume of the ready to use solution with a predetermined concentration of the sterile product reconstituted in the bag.

Claim 8 (Previously Presented): A bag according to claim 6, wherein a volume of the ready to use solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization.

Claim 9 (Previously Presented): A sealed bag constructed of flexible polyolefin material and configured to contain a ready to use solution reconstituted in the sealed bag by introducing within the sealed bag originally containing a dosed amount of a soluble sterile product in powder form an amount of solvent adapted to give the ready to use solution a desired concentration of the sterile product, wherein a capacity of the sealed bag is larger than a volume of the ready to use solution after the ready to use solution is reconstituted in the sealed bag.

Claim 10 (Previously Presented): A bag according to claim 9, wherein a capacity of the bag is between 1.5 and 2 times the volume of the ready to use solution reconstituted in the sealed bag.

Claim 11 (Previously Presented): A bag according to claim 9, wherein the volume of the ready to use solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization.

Claim 12 (Previously Presented): A method for preparing solutions with predetermined concentrations of soluble sterile product in powder form enclosed and sealed within a sterile bag constructed of flexible polyolefin materials, comprising:

feeding into the bag, containing a dosed amount of soluble sterile product in powder form adapted to give a solution of a predetermined concentration, an amount of solvent

adapted to reconstitute a ready to use solution with a desired concentration of the sterile product, a capacity of the bag being larger than a volume of the ready to use solution after the ready to use solution is reconstituted in the bag; and

removing from the bag the reconstituted ready to use solution in individual dose sizes.

Claim 13 (Previously Presented): A method according to claim 12, wherein the volume of the ready to use solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization.

Claim 14 (Previously Presented): A method for preparing solutions with predetermined concentrations of soluble sterile product in powder form enclosed and sealed within a sterile bag constructed of flexible polyolefin materials, comprising:

feeding into the bag, containing a dosed amount of soluble sterile product in powder form adapted to give a solution of a predetermined concentration, an amount of solvent adapted to reconstitute a ready to use solution with a desired concentration of the sterile product such that the fed amount of solvent is less than a capacity of the bag; and

removing from the bag the reconstituted ready to use solution in individual dose sizes.

Claim 15 (Previously Presented): A method according to claim 14, wherein a volume of the ready to use solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization.

Claim 16 (Previously Presented): A method for preparing solutions with predetermined concentrations of soluble sterile product in powder form enclosed and sealed within a sterile bag constructed of flexible polyolefin materials, the bag containing a dosed

amount of soluble sterile product in powder form adapted to give a solution of a predetermined concentration, comprising:

feeding into the bag an amount of solvent adapted to reconstitute a ready to use solution with a desired concentration of the sterile product, such that the fed amount of solvent is less than a capacity of the bag and such that a capacity of the bag is larger than a volume of the ready to use solution after the ready to use solution is reconstituted in the bag; and

removing from the bag the reconstituted ready to use solution in individual dose sizes.

Claim 17 (Previously Presented): A method according to claim 16, wherein the volume of the ready to use solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization.

Claim 18 (Previously Presented): A method according to claim 14, wherein the fed amount of solvent is 2/3 to 1/2 of the capacity of the bag.

Claim 19 (Previously Presented): A method according to claim 16, wherein the fed amount of solvent is 2/3 to 1/2 of the capacity of the bag.

Claim 20 (Previously Presented) A method for using a sterile bag constructed of flexible polyolefin materials containing a dosed amount of soluble sterile product in powder form adapted to give a solution of a predetermined concentration, comprising:

feeding into the bag, containing a dosed amount of soluble sterile product in powder form adapted to give a solution of a predetermined concentration, an amount of solvent

adapted to reconstitute a ready to use solution with a desired concentration of the sterile product such that the fed amount of solvent is less than a capacity of the bag; and

removing from the bag the reconstituted ready to use solution in individual dose sizes.

Claim 21 (Previously Presented): A method according to claim 20, wherein a volume of the ready to use solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization.

Claim 22 (Previously Presented): A method according to claim 20, wherein the fed amount of solvent is 2/3 to 1/2 of the capacity of the bag.

Claim 23 (Previously Presented): A method for using a sterile bag constructed of flexible polyolefin materials, the bag containing a dosed amount of soluble sterile product in powder form adapted to give a solution of a predetermined concentration, comprising:

feeding into the bag an amount of solvent adapted to reconstitute a ready to use solution with a desired concentration of the sterile product, such that the fed amount of solvent is less than a capacity of the bag and such that a capacity of the bag is larger than a volume of the ready to use solution after the ready to use solution is reconstituted in the bag; and

removing from the bag the reconstituted ready to use solution in individual dose sizes.

Claim 24 (Previously Presented) A method according to claim 23, wherein the volume of the ready to use solution reconstituted in the bag is a multiple of single doses of the ready to use solution directly usable for practical utilization.

Claim 25 (Previously Presented): A method according to claim 23, wherein the fed amount of solvent is 2/3 to 1/2 of the capacity of the bag.